REMARKS

In the Office Action dated May 8, 2007 claims 1, 3-4, 7-9, 11-12, 14, 28, and 35 were pending of which claims 1, 4, 7-9, 11-12, 14, 28, and 35 were rejected. Claims 36-47 are added by this Amendment. Claims now pending are 1, 3-4, 7-9, 11-12, 14, 28 and 35-47. Claim 14 is rejected under 35 U.S.C. § 112, second paragraph as indefinite. Claims 1, 4, 7-9, 11-12, 14, and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,716,183 to Clayman et al. ("*Clayman*") in view of U.S. Patent No. 5,295,493 to Radisch, Jr. ("*Radisch*") and further in view of U.S. Patent No. 4,925,445 to Sakamoto, et al. ("*Sakamoto*"). Claims 28 and 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable under *Clayman* in view of *Radisch* further in view of *Sakamoto* and even further in view of U.S. Patent No. 6,165,140 to Ferrera ("*Ferrera*").

Applicants respectfully traverse these rejections. It is noted with appreciation that claim 3 is not now rejected.

I. 35 U.S.C. § 112

Claim 14 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner alleges that it is unclear whether or not the distal curve extends from the distal zone or whether the distal curve extends from a portion of the central zone, in which case the distal curve overlaps both the distal zone and the central zone and therefore is not merely included in the distal zone.

The language of claim 1 recites that "a distal zone of transition . . . and wherein the distal zone comprises a distal pre-formed curve . . . ." Accordingly, the pre-formed curve in claim 1 is located within the distal zone. Claim 14

recites, "the distal curve comprises a portion of the central zone, the semi stiff zone adjacent to the central zone and a portion of the transition zone." In claim 14, the distal curve spans a portion of the central zone, the semi-stiff zone and a portion of the transition zone. For support of this interpretation, the Applicants point the Examiner to ¶ 56 of the specification, and specifically the portion which states that "[t]he distal zone 5 has a distal curve 6 which forms a substantial semicircle which encompasses part of the central zone 3 the semi-stiff zone 11 and part of the transition zone 13." Accordingly, the Applicants submit that claim 14 is definite and does particularly point out and distinctly claim the subject matter which the Applicants regard as their invention. The Applicants respectfully request the withdrawal of this rejection.

II. 35 U.S.C. § 103(a): Claims 1, 4, 7-9, 11-12, 14, 28, and 35

A. Claims 1, 4, 7-9, 11-12, 14, and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Clayman* in view of *Radisch* and further in view of *Sakamoto*. The Applicants respectfully traverse this rejection.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the cited references. *See*, MPEP § 2143.03. In addition, all words in a claim must be considered in judging the patentability of the claims over the cited references. *Id.* If an independent claim is nonobvious, then any claim depending from that claim is also nonobvious. *Id.*

Claims 4, 7-9, 11-12, 14, and 28 depend from claim 1. Claim 1, as previously amended, defines "a guide wire having zones of varying stiffness comprising: an elongate central zone of high stiffness to semi-stiffness . . . a proximal zone of transition from high stiffness to semi-stiffness . . . and a distal zone of transition from high stiffness to being relatively flexible . . . comprised of three zones: a semi stiff zone adjacent to the central zone; a transition zone

being of flexibility of from semi-stiff extending to flexible; and a tip zone being of high flexibility . . . ." The Applicants submit that the combination of all of these features is not present in *Clayman*, *Radisch*, or *Sakamoto*, individually or in proper combination.

The Examiner contends that all but one of the elements of the Application are taught in *Clayman*. *Clayman* discloses a urological guide wire having a distal section with a first flexibility, a central section with a second flexibility, and a proximal section with a third flexibility. (Col. 4, ll. 9-15). The flexibility of the distal section is relatively great and greater than the flexibility of the central section. The flexibility of the proximal section is less than that of the distal section, but greater than that of the central section. (Col. 4, ll. 25-33). The distal section 21 provides a high degree of flexibility and facilitates initial insertion of the guide wire through the tortuous path of the urinary conduit. (*See* col. 4, ll. 54-58). *Clayman*, however, does not disclose "a distal zone of transition from high stiffness to being relatively flexible . . . comprised of three zones: a semi stiff zone adjacent to the central zone; a transition zone being of flexibility of from semi-stiff extending to flexible; and a tip zone being of high flexibility . . . ." Furthermore, *Clayman* does not disclose a "tip zone of high flexibility and wherein the tip zone has a tip curve . . . ." Thus, the Examiner's assertion that *Clayman* discloses all but one of the elements of claim 1 is erroneous.

Moreover, these deficiencies are not cured by the addition of *Radisch*. *Radisch* discloses an anatomical guide wire having a predetermined anatomically shaped configuration for introducing an atherectomy cutter into a coronary artery for removing stenosis from the artery. The guide wire is an elongated structure which is made of a suitable strong material that can be formed and maintained in a desired shape. (Col. 4, ll. 15-20). The distal end of the guide wire is formed in

a three dimensional shape that conforms to the three dimensional arterial path into the heart. (*See* Col. 4, ll. 50-57). The guide wire must be introduced using an introducer catheter and a guiding catheter as a result of the inflexibility of the distal end of the guide wire. (*See* col. 6, ll. 33-37). Similarly, the guide wire must be withdrawn though a guiding catheter in order to eliminate any binding or snagging of wire in the right coronary artery that might otherwise occur. (Col. 7, ll. 1-6).

The Examiner purports that "Radish, Jr. discloses a guide wire comprising a distal zone wherein the distal zone comprises a distal pre-formed curve (22, 30, 40, 30a) with a radius . . . ." (Office Action, Mailed 5/8/2007). Moreover, the Examiner contends that it would have been obvious to provide a guide wire similar to that of *Clayman* "with a pre-formed curve distal zone similar to that of Radisch, Jr. so that the guide wire conforms to the general anatomical shape of the body cavity . . . ." (Office Action, Mailed 5/8/2007).

The Applicants submit, however, that the addition of Radish still does not teach "a distal zone of transition from high stiffness to being relatively flexible . . . comprised of three zones: a semi stiff zone adjacent to the central zone; a transition zone being of flexibility of from semi-stiff extending to flexible; and a tip zone being of high flexibility . . . ." Moreover, the proposed combination would render *Clayman* unsatisfactory for its intended purpose. *See* MPEP § 2143.01. The addition of the inflexible pre-formed curve of *Radish* to the distal section of the guide wire of *Clayman* would defeat one of the intended purposes cited by *Clayman* - specifically that "[t]he flexibility of the guidewire 10 is greatest in the distal section 16 and facilitates initial insertion of the guidewire 10 through the tortuous path of the urinary conduit." (Col. 4, ll. 54-56).

Although the Examiner has combined the teachings of *Clayman* with *Radish*, he has not articulated any reason why this combination would have been obvious. *In re Khan*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). Neither reference creates an inference or a creative step that a person of ordinary skill in the art would employ to combine these references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, Lexis 4745, at *32 (Apr. 30, 2007); *Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007).

Moreover, the claimed addition of *Radish* would also change the principal of operation of *Clayman*, as discussed above. *See* MPEP § 2143.01.

Finally, these deficiencies are not overcome by the addition of *Sakamoto*. *Sakamoto* discloses a guide wire for a catheter having a distal end portion comparatively flexible that is formed out of a super-elastic metallic member. *Sakamoto* states that "[t]he guide wire 10 has no irregularities on the surface thereof, differing from the conventional coil-shaped guide wire . . . [and] [t]he guide wire 10 is satisfactory in torque transmission performance in either one of torsional directions, differing from the conventional coil-shaped guide wire." (Col. 7, ll. 45-55). Again, the Examiner has not articulated any reason why the addition of *Sakamoto* would have been obvious. *In re Khan*, 441 F.3d at 988. Since the guide wire disclosed in *Clayman* has "a distal tip 32 . . . [that] can be covered by a wire coil 34," it would be improper to combine *Sakamoto* with the Clayman, as *Sakamoto* teaches away from the use of coil-shaped guide wire. (Col. 5, ll. 19-25); *In re Grasselli*, 713 F.2d 731 (Fed. Cir. 1983).

The deficiencies discussed with respect to *Clayman* and *Radish* are not cured by the addition of *Sakamoto*, as *Sakamoto* also fails to disclose "a distal zone of transition from high stiffness to being relatively flexible . . . comprised of three zones: a semi stiff zone adjacent to the central zone; a transition zone being of flexibility of from semi-stiff extending to flexible; and a tip zone being of high flexibility . . . ." Furthermore, *Sakamoto* fails to disclose "a distal pre-formed curve with a radius of curvature of from 5 cm to 15 cm."

It is for at least these reasons independent claim 1 is patentable over *Clayman*, *Radish*, and *Sakamoto*, alone or in proper combination. It logically follows that dependent claims 4, 7-9, 11-12, 14 and 28 are also in condition for allowance as each of the dependent clams have additional limitations. For example, and without limitation, dependent claim 14 further requires that "the distal curve comprises a portion of the central zone, the semi stiff zone adjacent the central zone and a portion of the transition zone." Clearly, if the proposed combination of *Clayman*, *Radish*, and *Sakamoto* does not disclose all of the elements as required by claim 1, it surely cannot, and in fact does not, disclose the additional limitation of claim 14. Accordingly, claim 14 is further patentable over *Clayman*, *Radish*, and *Sakamoto*.

In view of these important distinctions, the combination of *Clayman*, *Radish*, and *Sakamoto* would not have made Appellants' invention obvious.

B. Claims 28 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Clayman* in view of *Radisch* further in view of *Sakamoto* and even further in view of U.S. Patent No. 6,165,140 to Ferrera ("*Ferrera*"). Claims 28 and 35 depend from claim 1. As discussed above, *Clayman*, *Radisch*, and

Sakamoto, alone or in combination, still do not disclose all of the elements of the claimed invention. Those deficiencies are not cured by the addition of *Ferrera*.

Ferrera discloses a composite guide wire that includes an elongated, flexible core formed from a nickel titanium alloy, having a proximal region and a distal region. *Ferrera* does not disclose, among other elements, "a distal zone of transition from high stiffness to being relatively flexible . . . comprised of three zones: a semi stiff zone adjacent to the central zone; a transition zone being of flexibility of from semi-stiff extending to flexible; and a tip zone being of high flexibility and wherein the tip zone has a tip curve . . . ."

Because the combination, assuming *arguendo* it is proper, of *Clayman*, *Radish*, *Sakamoto*, and *Ferrera*, does not teach all of the claim limitations of independent claim 1, it logically follows that dependent claims 28 and 35 are also in condition for allowance. Indeed, because each of these dependent claims have additional limitations, they are further patentable over the cited references. For example, and without limitation, dependent claim 34 further requires "the proximal zone comprises a proximal wire coil of substantially constant coil diameter and the distal zone comprises a distal wire coil of substantially constant coil diameter" and therefore is further patentable over *Clayman*, *Radish*, *Sakamoto*, and *Ferrera*.

In view of these important distinctions, the combination of *Clayman*, *Radish*, *Sakamoto*, and Ferrera would not have made Appellant's invention obvious.

C. It is noted with appreciation that Claim 3 is not now rejected, even though the summary on page 1 of the Office Action states that claim 3 is rejected.

III. Addition of Claims 36-47

The Applicants have added claims 36-47. No new matter was added by this amendment. Added claims 36-47 have support in the specification, as detailed below.

Independent claim 36 is directed towards: "A guide wire to assist percutaneous endovascular deployment comprising: . . . a distal portion of the mandrel comprising in order from the central zone, a distal tapered portion, and a portion of constant reduced diameter with a distal wire coil on and extending along the distal tapered portion and the portion of constant reduced diameter."

Support for independent claim 36 can be found on page 12, ll. 7-17 and page 13, l. 27 – page 14, l. 9 of the specification and Figures 8-9, where one embodiment of the invention is illustrated. The prior art does not each "a distal portion of the mandrel comprising in order from the central zone, a distal tapered portion, and a portion of constant reduced diameter with a distal wire coil on and extending along the distal tapered portion and the portion of constant reduced diameter," as required by independent claim 36.

Claims 37 - 40 are dependent from claim 36 and support for claim 37 can be found on page 12, ll. 7-17 of the specification. Support for claim 38 can be found page 4, ll. 24-25 of the specification, support for claim 39 is found on page 5, ll. 7-10, and support for claim 40 is found on page 13, ll. 5-10.

Independent claim 41 is directed towards: "A guide wire that has . . . 5 zones of differing stiffness, a first zone constituting a distal tip and being very floppy and atraumatic; a second zone . . . going from floppy to stiff; the third zone . . . being a semi-stiff region; the fourth zone . . . being . . . very stiff; and the fifth zone . . . being a transition zone from very stiff to semi-stiff at the proximal-most end of the guidewire."

Support for independent claim 41 is found on page 8, ll. 10-27 and one embodiment of the claimed invention is shown in Figures 1 and 2. The prior art does not teach or suggest a "guide wire that has . . . 5 zones" which vary in stiffness.

Claims 42 – 47 all depend from claim 41, and include further limitations that distinguish the claims over the prior art. For example, dependent claim 43 further requires "having a large-radius secondary curve that incorporates the transition to semi-stiff zone, the semi-stiff zone and the distal part of the stiff or body portion, sized to roughly fit the curvature of the aorta." Support for dependent claim 43 is found on page 9, l. 28 – page 10, l. 14 and Figures 3 and 4. Support for dependent claim 44 can be found on page 12, ll. 4-6, support for claim 45 can be found on page 4, ll. 24-25, support for claim 46 can be found on page 13, ll. 5-10, and support for claim 47 can be found on page 5, ll. 7-10.

IV. Conclusion

In light of the above, Applicants submit that claims 1, 4, 7-9, 11, 12, 14, 28, and 35-47 are in condition for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,

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